IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case No. 4:16-cv-048 (Kwiatkowski)

O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Paula Kwiatkowski was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Kwiatkowski brought a product liability action against Mentor, contending that ObTape had design and manufacturing defects that proximately caused her injuries. Kwiatkowski also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape.

The parties agree that Minnesota law applies to Kwiatkowski's claims because Kwiatkowski is a Minnesota resident whose ObTape-related treatment occurred in Minnesota. The parties further agree that the statute of limitations for Kwiatkowski's strict liability claims is four years, and the statute of limitations for her negligence claims is six years. *See* Minn. Stat. § 541.05 subd. 2 ("[A]ny action based on the

strict liability of the defendant and arising from the manufacture, sale, use or consumption of a product shall be commenced within four years."); Minn. Stat. § 541.05 subd. 1(5) (establishing six-year limitation period for personal injury claims not arising in contract or strict liability). The parties do not, however, agree on when a personal injury claim based on injuries allegedly caused by a defective implantable medical device accrues under Minnesota law. Mentor moved to certify the question to the Minnesota Supreme Court.

Under Minnesota law, the Minnesota Supreme Court "may answer a question of law certified to it by a court of the United States . . . if the answer may be determinative of an issue in pending litigation in the certifying court and there is no controlling appellate decision, constitutional provision, or statute of this state." Minn. Stat. Ann. § 480.065 Subd. 3. Mentor's request for certification has some superficial appeal because there is no controlling precedent from the Minnesota Supreme Court on the proper standard for accrual of product-based personal injury claims under Minnesota law. The Court has found this issue to be determinative in many other cases in this multidistrict litigation proceeding. But resolution of a summary judgment motion in *this* action does not turn on the proper accrual standard. Rather, it turns on the facts. Because it appears from the present record that the Court would

deny summary judgment even under the strict accrual standard advocated by Mentor, the motion to certify (ECF No. 12) is denied.

FACTUAL BACKGROUND

Mentor did not file a summary judgment motion, but Mentor did submit a statement of relevant facts in support of its motion to certify, and Kwiatkowski responded with her own statement of facts. Both sides supported their fact statements with evidentiary submissions. The Court has reviewed the fact statements and citations to the record as it would review a similar record on a summary judgment motion: viewed in the light most favorable to Kwiatkowski. The present record reveals the following.

Plaintiff Paula Kwiatkowski is a Minnesota resident who suffered from stress urinary incontinence. On July 12, 2004, Kwiatkowski was surgically implanted with ObTape, a synthetic mesh sling device, to treat her stress urinary incontinence. Pl.'s Am. Fact Sheet ¶ 2, ECF No. 12-6 in 4:16-cv-048. Kwiatkowski's implant surgery and other ObTape-related treatment took place in Minnesota. ObTape is a non-woven, thermally bonded polypropylene mesh tape, and Kwiatkowski asserts that its physical properties cause ObTape to admit bacteria, hinder immune cells, and fail to achieve tissue in-growth. Due to these and other issues, ObTape is susceptible to complications

like infections and erosion of the ObTape through a patient's bodily tissues. Although erosion and infection are risks of any sling product, Kwiatkowski asserts that the risk is higher with ObTape but that Mentor failed to warn her physicians about the true risks of ObTape. She also asserts that she suffered from complications that were caused by defects in ObTape.

Shortly after her implant surgery, Kwiatkowski's doctor twice diagnosed her with a vaginal dehiscence, which means that Kwiatkowski's surgical incision reopened. Ashford Dep. 87:14-23, ECF No. 13-2 in 4:16-cv-48. Although Kwiatkowski understood that she needed to have a revision surgery to fix the problem when it happened in August 2004 and again in November 2004, neither she nor her doctor concluded that ObTape caused the incision to reopen. *Id.* at 90:19-25 ("Well, in her case, because it looked like . . . this was probably not a mesh problem, but I was looking at this as a regular incision dehiscence problem. So I didn't think of it as a repair of a mesh erosion at the time. I was thinking her incision opened for some reason that had nothing to do with the [mesh]."). Based on this evidence, a reasonable juror could conclude that Kwiatkowski did not suffer an injury *caused by* ObTape in 2004.

After the dehiscence repairs in 2004, Kwiatkowski's incontinence improved for a while, but it got worse again in 2006. By 2008, Kwiatkowski was concerned that the ObTape was

not working correctly. And in 2010, Kwiatkowski underwent a second sling procedure; her doctor removed those portions of the ObTape that were not embedded, and he implanted a different sling. There is no evidence in the present record that ObTape was causing adverse symptoms, such as pain or discharge. There is also no evidence in the present record that ObTape caused Kwiatkowski's recurrent stress urinary incontinence or that its partial removal as part of the 2010 sling placement was necessary to correct some problem caused by ObTape.

DISCUSSION

The Minnesota Supreme Court "may answer a question of law certified to it by a court of the United States . . . if the answer may be *determinative of an issue in pending litigation* in the certifying court and there is no controlling appellate decision, constitutional provision, or statute of this state." Minn. Stat. Ann. § 480.065 Subd. 3 (emphasis added). Mentor is correct that there is no controlling Minnesota authority on the proper accrual standard for a personal injury claim based on an alleged product defect. But, at a minimum, Minnesota law requires that "two elements must be satisfied before a cause of action accrues in cases involving injuries caused by a defective product: '(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection between the injury or disease and the defendant's product, act, or

omission.'" *Rogers v. Mentor Corp.*, 682 F. App'x 701, 709 (11th Cir. 2017) (quoting *Klempka v. G.D. Searle & Co.*, 963 F.2d 168, 170 (8th Cir. 1992)) (applying Minnesota law).[1]

Here, there is no evidence in the present record that Kwiatkowski suffered an injury that she knew or had reason to know was *caused by* ObTape more than four years before she filed this action. There is no evidence that the two revision procedures in 2004 were necessitated by an erosion or infection of the ObTape as opposed to some other surgical complication that caused Kwiatkowski's incision to reopen. A genuine factual dispute exists as to whether ObTape was the mechanism that contributed to the complications Kwiatkowski suffered almost immediately after the implant surgery. A reasonable jury could, perhaps, conclude that ObTape caused the incision to reopen. But Mentor did not point to sufficient evidence for the Court to exclude the reasonable possibility that the incision issues were unrelated to the ObTape, or that the surgical procedure itself contributed to the problems Kwiatkowski suffered. And, although

[1] The U.S. Court of Appeals for the Eleventh Circuit concluded, in an unpublished opinion, that Minnesota law mirrors Georgia law and that a product-related personal injury claim does not accrue until the plaintiff is aware of a causal connection between the plaintiff's injuries and a *problem* with the product. *Rogers v. Mentor Corp.*, 682 F. App'x 701, 710 (11th Cir. 2017). In other words, the statute of limitations does not accrue until the plaintiff is aware of a causal connection between her injuries and the product, as well as a causal connection between her injuries and some type of misconduct by the defendant related to the product. The Court need not evaluate whether there is a genuine fact dispute under this standard because there is a genuine fact dispute under the stricter standard advocated by Mentor.

Mentor appears to suggest that Kwiatkowski undisputedly suffered injuries caused by ObTape when she had a second sling procedure in 2010, there is no evidence in the present record that ObTape caused Kwiatkowski's recurrent stress urinary incontinence or that its partial removal as part of the 2010 sling placement was necessary to correct some problem caused by ObTape. For all of these reasons, a genuine factual dispute exists as to when Kwiatkowski suffered an ObTape-related physical injury that would commence the running of the statute of limitations under Minnesota law, even under the strict standard advocated by Mentor.

CONCLUSION

In light of the interpretation of Minnesota law by a panel of the Eleventh Circuit Court of Appeals, this Court would welcome guidance from the Minnesota Supreme Court on the proper standard for accrual of product-based personal injury claims under Minnesota law. But the Court cannot certify the question to the Minnesota Supreme Court in this case because the answer to the question would not make a difference in the outcome. As discussed above, even if the standard advocated by Mentor applies, there is a genuine fact dispute on when Kwiatkowski suffered an injury caused by ObTape, and it is not clear as a matter of law that she knew or had reason to know that she suffered an injury caused by ObTape more than four years before

she filed this action. Because it appears from the present record that the Court would deny summary judgment even under the accrual standard advocated by Mentor, the motion to certify (ECF No. 12) is denied.

TRANSFER OF ACTION

Kwiatkowski filed this action pursuant to the Court's Direct Filing Order in MDL No. 2004. *See* Order Regarding Direct Filing § II(A), ECF No. 446 in 4:08-md-2004 (permitting plaintiffs from outside the Middle District of Georgia whose cases "would be subject to transfer to MDL No. 2004" to file their cases "directly in the MDL proceedings in the Middle District of Georgia"). The action was "filed in MDL No. 2004 for pretrial proceedings only, consistent with the Judicial Panel on Multidistrict Litigation's December 3, 2008, Transfer Order." *Id.* § II(B). All discovery has been completed, and this case is ready for trial.

Given that Mentor has not elected to waive venue under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998) since early 2016, the Court finds it appropriate to transfer this action to the court where venue is proper, the U.S. District Court for the District of Minnesota. *See* Compl. ¶ 5, ECF No. 1 (stating that Kwiatkowski would have filed this action in Minnesota had she not filed it in this Court under the direct filing order). For the convenience of that court, the

appendix to this Order contains a brief chronicle of the coordinated proceedings, as well as a list of significant filings and orders in MDL No. 2004.

The Clerk of Court is directed to provide a copy of this Order to the Clerk of the Judicial Panel on Multidistrict Litigation.

IT IS SO ORDERED, this 20th day of October, 2017.

S/Clay D. Land
CLAY D. LAND
CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA

APPENDIX

I. Brief Background of the Mentor ObTape MDL

Mentor Worldwide LLC manufactured and sold a polypropylene mesh suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. The United States Food and Drug Administration cleared ObTape for sale in 2003 via its 510(k) regulatory process, and ObTape remained on the market in the United States until March 2006.

About ten years ago, women who had been surgically implanted with ObTape began filing lawsuits against Mentor, alleging that they had been injured by ObTape—primarily that they suffered infections caused by ObTape and that they were injured when ObTape eroded through their bodily tissues. In December 2008, the Judicial Panel on Multidistrict Litigation created MDL No. 2004 and transferred seventeen actions involving alleged injuries resulting from ObTape to this Court for consolidated and coordinated pretrial proceedings. *See In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 588 F. Supp. 2d 1374 (J.P.M.L. 2008). After pretrial proceedings and a bellwether trial that settled mid-trial, the original cases and approximately forty additional tag-along cases transferred to this Court were resolved through settlement. Since then, MDL No. 2004 has grown to include more

than 800 additional tag-along cases, although only a few remain open. The litigation was divided into phases, and cases from phase IV-10 are still pending. In 2013, the Court tried a Phase III bellwether case to verdict. In 2016, the Court tried a Phase IV-1 bellwether case to verdict.

II. Significant Filings in MDL No. 2004

These filings are, for the most part, evidentiary rulings that were made in the context of the bellwether cases that were tried in this Court; these issues may arise again.

1. Order Denying Motion to Disqualify Expert Witness Dr. Catherine Ortuno, Apr. 1, 2010. ECF No. 231 in 4:08-md-2004; 2010 WL 1416548.
   Summary: Mentor sought to exclude the testimony of Dr. Catherine Ortuno, who was an employee of a French Mentor subsidiary called Porges. While she was employed by Porges, Dr. Ortuno and a colleague developed concerns about the safety of ObTape and ultimately recommended that sales of ObTape be stopped. The Court concluded that Dr. Ortuno would be permitted to serve as an expert witness for Plaintiffs but that she would not be permitted to offer any testimony that would divulge privileged, attorney-client communications.

2. Order on Phase I Summary Judgment Motions and Admissibility of Plaintiffs' Experts, Apr. 22, 2010. ECF No. 241 in 4:08-md-2004; 711 F. Supp. 2d 1348.
   Summary: Mentor sought to exclude Plaintiffs' experts under Federal Rule of Evidence 702.
   Dr. Catherine Ortuno – motion denied; the Court found that Dr. Ortuno's methodology was sufficiently reliable.
   General Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. Michel Cosson, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, Dr. Donald Ostergard, Dr. William Porter, and Dr. Andrew Siegel) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
   Specific Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. John Davis, Dr. James Hiller, Dr.

Mickey Karram, Dr. Kenneth Mitchell, and Dr. Mark Slack) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
Dr. George Samaras – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Samaras would be permitted to testify on general causation but not specific causation.
Dr. Ahmed El-Ghannam – motion denied; the Court found that Dr. El-Ghannam's opinions were sufficiently reliable.
Dr. Paul Ducheyne – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Ducheyne could not testify regarding what caused degradation in ObTape but could testify that Mentor should have done more testing based on Mentor's awareness that ObTape could degrade.
Dr. Arnold Lentnek – motion deferred pending *Daubert* hearing. On May 12, 2010, the Court decided to permit Dr. Lentnek's testimony (ECF No. 301 in 4:08-md-2004).

3. Order re Evidence Related to FDA Regulatory Process, Apr. 23, 2010. ECF No. 242 in 4:08-md-2004; 2010 WL 1734638.
Summary: Plaintiffs sought to exclude evidence related to the FDA regulatory process. Discussed basic rules regarding evidence of FDA regulatory process. Deferred ruling until pretrial conference. At the pretrial conference on May 3, 2010, the Court granted the motion in limine but stated that if Plaintiffs opened the door to the FDA evidence, it could come in. (ECF No. 299 – Transcript 174:9-175:16).

Note: the Court admitted 510(k) evidence during the 2013 trial of *Morey v. Mentor*, 4:11-cv-5065 but gave a limiting instruction on this issue. *Morey*, Jury Instructions Charge No. 11, ECF No. 183 in 4:11-cv-5065. But the Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.

4. Order re Phase I Plaintiffs' Experts, Apr. 27, 2010. ECF No. 246 in 4:08-md-2004; 2010 WL 1727828.
Summary: Mentor sought to exclude the testimony of Plaintiffs' experts under Federal Rule of Evidence 702 and based on relevance. The motion was granted in part and denied in part.

Dr. Ann Buchholtz – testimony not permitted.
Rabbit Study – testimony explaining rabbit study permitted, but not testimony that rabbit study establishes that ObTape is capable of causing similar conditions in humans.
Mentor's Warnings to Physicians and the FDA – testimony may be relevant to failure to warn claim, but Plaintiff must establish relevance before eliciting this testimony.

5. Order re Phase I Experts, Apr. 29, 2010. ECF No. 282 in 4:08-md-2004; 2010 WL 1782272.
Summary: The parties sought to exclude expert testimony of each other's experts under Federal Rule of Evidence 702. The motions were denied.
Dr. Michael Chernick (Plaintiffs' statistician) – testimony permitted.
Mentor's Specific Causation Rebuttal Witnesses (Dr. Marta Villarraga, Dr. Charles L. Secrest, Dr. A.W. Karchmer, Dr. James M. Anderson) – testimony permitted.
Dr. Marta Villarraga (Mentor's expert re Mentor's conduct in bringing ObTape to Market) – testimony permitted.
Mentor's Experts regarding Pore Distribution **(**Drs. Villarraga and Clevenger) – testimony permitted.

6. Phase I Bellwether Pretrial Conference Transcript (Day 1), May 3, 2010. ECF No. 299 in 4:08-md-2004. Ruled from the bench on several motions in limine.
Significant Issues:
- Cross Motions to Exclude Evidence re FDA Regulatory Process (ECF Nos. 249 & 259) – Granted. Hr'g Tr. 164:11-175:16. Written opinion on this issue December 3, 2015. *See infra* § III.18.i.
- Plaintiffs' Motion to Exclude "Complication Rates" (ECF Nos. 250 & 251) – Denied. Hr'g Tr. 175:20-178:19.

7. Phase I Bellwether Pretrial Conference Transcript (Day 2), May 4, 2010. ECF No. 300 in 4:08-md-2004. Ruled from the bench on several motions in limine.
Significant Issue:
Mentor's Motion to Exclude Evidence Adverse Event Reports (ECF No. 273) – Denied, but reports must be redacted. Hr'g Tr. 42:7-47:8.

8. Order re Dr. Arnold Lentnek, May 12, 2010. ECF No. 301 in 4:08-md-2004.
Summary: Denied Mentor's motion to exclude Dr. Lentnek, concluding that Dr. Lentnek's methodology was sufficiently reliable.

9. Order to "Tie Up Some Loose Ends" after Pretrial Conference, May 18, 2010. ECF No. 335 in 4:08-md-2004, 2010 WL 1998166.
Summary: addressed several issues. Significantly, the Court stated that it would permit recording of the testimony of European witnesses so the recordings could be used in later trials of MDL No. 2004 cases. Also addressed the trial structure and concluded that trial should be bifurcated (Phase 1: compensatory damages/punitive damages entitlement; Phase 2: punitive damages amount).

Note: part of this Order was later vacated (*see* ECF 350 re continuing duty to warn under Georgia law).

10. Order re Subsequent Remedial Measure, May 20, 2010. ECF No. 341 in 4:08-md-2004, 2010 WL 2015146.
Summary: Concluded that Mentor's decision to stop selling ObTape is a subsequent remedial measure under Federal Rule of Evidence 407, so evidence of this decision is not admissible "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction" but may be admitted for another purpose. Also concluded that Mentor's introduction of a new sling product, Aris, was *not* a subsequent remedial measure under Federal Rule of Evidence 407.

11. Order re Similar Complications, May 28, 2010. ECF No. 351 in 4:08-md-2004, 2010 WL 2196632.
Summary: Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

12. Order Appointing Plaintiffs' Liaison Counsel and Co-Lead Counsel, Sept. 21, 2011. ECF No. 422 in 4:08-md-2004.

13. Order Establishing Plaintiffs' Litigation Expense Fund and Common Benefit, Aug. 9, 2012. ECF No. 493 in

4:08-md-2004. This agreement is between Plaintiffs' counsel and addresses the sharing among Plaintiffs of the cost of special services performed and expenses performed for the common benefit of the Plaintiffs of MDL No. 2004.

14. Text Order re Dr. Ahmed El-Ghannam, June 4, 2013 in *Morey v. Mentor*, 4:11-cv-5065. Explained that general causation witness's must be tied to the Plaintiff: "To introduce [Dr. El-Ghannam'] testimony regarding ObTape degradation and/or the release of toxins, the witness must establish a causal connection between that degradation and/or release of toxins and Plaintiff's infection and extrusion/erosion."

15. Order re Post-Injury Evidence/Punitive Damages (in *Morey v. Mentor*), June 12, 2013. ECF No. 671 in 4:08-md-2004.
Summary: Concluded that, under Minnesota law, certain post-injury evidence is admissible on the issue of punitive damages.
16. Order re Withdrawal of ObTape from the Market (in *Morey v. Mentor*), June 12, 2013. ECF No. 673 in 4:08-md-2004.
Summary: Reiterated that the withdrawal of ObTape from the market was a subsequent remedial measure under Federal Rule of Evidence 407.

17. Jury Instructions and verdict form in *Morey v. Mentor*, June 13, 2013. ECF No. 183 in 4:11-cv-5065. **Notes:** Morey asserted a negligence claim under Minnesota law. The Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.
18. Order on Motions in Limine, Dec. 3, 2015 (in *Taylor*, 4:12-cv-176; *Sanborn*, 4:13-cv-42; and *Mack*, 4:14-cv-117), ECF No. 92 in 4:12-cv-176, 2015 WL 7863032.

Significant issues:

i. FDA 510(k) Evidence. Ruled that evidence of 510(k) preclearance process would not be admitted because even if it is relevant, the probative value is substantially outweighed by the risk of unfair prejudice and potential to confuse and mislead the jury.

ii. **Dr. Lentnek.** Ruled that Plaintiffs would have to establish "fit" prior to admission of Dr. Lentnek's testimony.

iii. **Dr. El-Ghannam.** Ruled that Plaintiffs would have to make proffer of specific causation before Dr. El-Ghannam could testify on certain issues.

iv. **Post-Implant Evidence.** Ruled that evidence of Mentor's conduct and awareness after Plaintiffs' implant date is admissible.

19. Order re Similar Complications (in *Taylor*, 4:12-cv-176; *Sanborn*, 4:13-cv-42; and *Mack*, 4:14-cv-117), Feb. 1, 2016. ECF No. 115 in 4:12-cv-176, 2016 WL 393958. **Summary**: Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

20. Jury Instructions and verdict form in *Taylor v. Mentor*, Feb. 18, 2016. ECF Nos. 172, 174 in 4:12-cv-176. **Note**: Taylor's claims were under Florida law.